CLAIMS

1. A method of diagnosing bone metastasis of malignant tumor using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

2. The method according to claim 1, wherein the marker that reflects the activity of osteoblasts is:

(1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or

(2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

3. The method according to claim 1 or 2, wherein the marker that reflects the activity of osteoblasts is:

(1) PICP or PINP and osteocalcin; or

(2) BALP and osteocalcin.

4. The method according to any one of claims 1 - 3, wherein the marker that reflects the action of osteoclasts is a marker associated with bone type I collagen.

5. The method according to any one of claims 1 - 4, wherein the marker that reflects the action of osteoclasts is deoxypyridinoline and/or ICTP.

6. The method according to any one of claims 1 - 5, which is based on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of osteoblast proliferation and matrix formation and the measured value of the marker that reflects the action of

- 18 -

osteoclasts, or on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of matrix maturation and the measured value of a marker associated with bone type I collagen.

7.   The method according to claim 6, which is based on the value of a crossover index between osteocalcin and PICP or PINP and the measured value of ICTP, or on the value of a crossover index between osteocalcin and BALP and the measured value of ICTP.

8.   A method of evaluating the therapeutic efficacy of a drug using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

9.   The method according to claim 8, wherein the drug is a cancer control therapeutic agent.

10.   The method according to claim 8, wherein the drug is a bone resorption suppressant.

11.   The method according to claim 8, wherein the drug is an endocrine therapeutic agent.

12.   The method according to any one of claims 8 - 11, wherein the marker that reflects the activity of osteoblasts is:

(1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or

(2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

- 19 -

13. The method according to ~~any one of claims 8 or~~ 12, *claim 8*
wherein the marker that reflects the activity of
osteoblasts is:

(1) PICP or PINP and osteocalcin; or

(2) BALP and osteocalcin.

14. The method according to ~~any one of claims 8 -~~ 13, *claim 8*
wherein the marker that reflects the action of osteoclasts
is a marker associated with bone type I collagen.

15. The method according to ~~any one of claims 8 -~~ 14, *claim 8*
wherein the marker that reflects the action of osteoclasts
is deoxypyridinoline and/or ICTP. *claim 8*

16. The method according to ~~any one of claims 8 - 15~~,
which is based on the value of a crossover index or the
ratio between a marker associated with the phase of
calcification and a marker associated with the phase of
osteoblast proliferation and matrix formation and the
measured value of the marker that reflects the action of
osteoclasts, or on the value of a crossover index or the
ratio between a marker associated with the phase of
calcification and a marker associated with the phase of
matrix maturation and the measured value of a marker
associated with bone type I collagen.

17. The method according to claim 16, which is based on
the value of a crossover index between osteocalcin and PICP
or PINP and the measured value of ICTP, or on the value of
a crossover index between osteocalcin and BALP and the
measured value of ICTP.

- 20 -